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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,777

06/10/2005

Ola Carlsson

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5515

22852

7590

10/08/2009

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EXAMINER

CONLEY, SEAN EVERETT

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

10/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,777	Applicant(s) CARLSSON ET AL.	
	Examiner SEAN E. CONLEY	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/13/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 and 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/18/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed July 13, 2009 has been received and considered for examination. Claims 1 and 3-30 are pending with claims 12-16 and 26-30 remaining withdrawn from consideration.

Double Patenting

2. The double patenting rejection of claims 1-11 and 17-25 on page 7 of the office action mailed on January 14, 2009 has been withdrawn since co-pending application 10/538,791 is now abandoned.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3-11 and 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al. (U.S. Patent No. 5,536,469) in view of Breborowicz et al. (document titled "Replacement of Glucose with N-Acetylglucosamine in Peritoneal Dialysis Fluid").

Jonsson et al. discloses a sterile medical solution containing glucose or glucose-like compounds for peritoneal dialysis (see col. 1, lines 54-56). The content of the

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glucose-like compounds are preferably in the order of 40% by weight (see col. 1, lines 60-65). Jonsson et al. further discloses heat sterilization of the final solution (see col. 2, line 2) between a temperature of 110°C and 150°C (see col. 2, line 10), specifically 121°C (see col. 5, lines 1-5). Heat sterilization necessarily involves some degree of heat transfer provided by convection, conduction, and thermal radiation in the form of non-ionizing infra-red radiation, and therefore interpreted broadly heat sterilization meets the definition of radiation sterilization. Jonsson et al. also discloses the final solution optimized at a pH between 6.5 and 7.5, preferably about 7.0 (see col. 2, lines 55-56) and the solution mixed and diluted to 1.5% glucose content after sterilization (see col. 2, lines 57-61). Jonsson et al. further discloses the solution contains low levels of cytotoxic degradation products (see col. 4, lines 3-5). Jonsson et al. discloses the solution in a bag system (see col. 4, lines 11-20) which is a container comprising at least one compartment.

However, Jonsson et al. does not specifically disclose a medical solution containing one or more acetylated or deacetylated amino sugars nor does Jonsson et al. specifically disclose the preparation of a final medical solution wherein the pH is 7.4.

Breborowicz et al. teaches partial replacement of glucose with N-acetylglucosamine (NAG) in peritoneal dialysis fluid results in advantageous preservation of the peritoneal membrane (see page 365, left column, paragraph 1). Breborowicz et al. also teaches supplementation of the dialysis fluid with hyaluronan, a human glucoseaminoglycan, results in the advantageous suppression of inflammatory reaction induced by peritoneal dialysis (see page 365, right column, paragraph 1).

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Jonsson et al. in view of Breborowicz et al.

One of ordinary skill in the art would be motivated to combine Jonsson et al. in view of Breborowicz et al. because Breborowicz teaches it is advantageous to partially replace glucose with N- acetylglucosamine (NAG) which is more biocompatible, giving a solution comprising both NAG molecules and the physiologically compatible constituents glucose molecules.

One of ordinary skill in the art would be motivated to practice the invention of Jonsson et al. in view of Breborowicz et al. wherein the one or more acetylated or deacetylated amino sugars is human glucoseaminoglycan because Breborowicz et al. teaches supplementation of the dialysis fluid with hyaluronan (a human glucoseaminoglycan) results in the advantageous suppression of inflammatory reaction induced by peritoneal dialysis.

One of ordinary skill in the art would be motivated to optimize the final medical solution wherein the pH is 7.4 because Jonsson et al. teaches the final peritoneal dialysis solution optimized at a pH between 6.5 and 7.5, and it is well known in the biological field that pH 7.4 is the common blood plasma pH and therefore an optimally biocompatible pH.

Response to Arguments

5. Applicant's arguments filed July 13, 2009 have been fully considered but they are not persuasive.

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Applicant first argues the following on page 10: *"One of ordinary skill in the art would not have had a reasonable expectation that the sterilization method for glucose in Jonsson would have been applicable to a solution comprising NAG".* The Applicant further argues the following: *"In the absence of some guidance regarding the thermal degradation of amino sugars, one of ordinary skill in the art would not have had an expectation of success when applying any of the known heat-sterilization protocols to solutions comprising amino sugars, including that of Jonsson."*

The Examiner respectfully disagrees. It is well known that N-acetylglucosamine has a melting point of 205 °C with no indication of decomposition (entry for 4466. Glucosamine, The Merck Index, 12th ed.), above that of the heat sterilization temperature of between 110 and 150 °C taught by Jonsson. Based on this known stability up to 205 °C of one of ordinary skill in the art would have a reasonable expectation of success in combining Jonsson in view of Breborowicz.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Conley whose telephone number is 571-272-8414. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 7, 2009

/Sean E Conley/
Primary Examiner, Art Unit 1797